TITLE:	**Determination of personal exposures to Environmental Tobacco Smoke in British non-smokers**
PRINCIPAL INVESTIGATOR:	**K Phillips**
KEY INVESTIGATORS:	**T Houseman** **D Howard** **J Freeman** **K Tennant** **J Moore** **G Bridger**
INSTITUTION:	**Hazleton UK**

2023473207

Source: https://www.industrydocuments.ucsf.edu/docs/njlm0000

RESEARCH ABSTRACT

Title of Project: Determination of personal exposures to Environmental Tobacco Smoke in British non-smokers.

Investigator(s): K Phillips, J Freeman and T H Houseman

Institution: Hazleton UK

ABSTRACT: In the space below, please provide a descriptive summary of your proposed research project.

We propose to investigate typical personal exposures of British non-smokers to Environmental Tobacco Smoke, ETS, through a variety of inter-related measures. There are two main reasons for this investigation. The first is that, although considerable data exist quantifying levels of various constituents of ETS in fixed environments, there is relatively little data describing typical total daily exposures. The second is that much of the existing personal exposure data rely on measures of cotinine, a metabolite of nicotine in the body fluids of non-smokers. The accuracy of this measure has been questioned and this study proposes to examine the relationship between levels of cotinine and measures of chemical exposure to several ETS constituents and to questionnaire responses.

The study would randomly select around 300 non-smokers. Each subject would be investigated for exposure to ETS over a 24 hour period. The measures would be a time-activity diary, a post-sampling questionnaire on perceived exposure, salivary cotinine levels (pre- and post-monitoring period) and personal exposures to nicotine and to particulates. The particulate sample would be analysed for ultra-violet, fluorescence and solanesol content as assessments of the contribution of ETS to the total particulates collected. It is anticipated that such a study would prove information useful to the determination of the extent of ETS exposure and to the assessment of best measures of such exposure.

K. Phillips — Signature, Principal Investigator

12 August 1992 — Date

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CENTER FOR INDOOR AIR RESEARCH
1099 WINTERSON ROAD SUITE 280 LINTHICUM MD 21090
(410) 684-3777 FAX (410) 684-3729

APPLICATION FOR RESEARCH CONTRACT

1 PRINCIPAL INVESTIGATOR. NAME, TITLE, TELEPHONE # AND MAILING ADDRESS

Tel: 44 423 500011
Fax: 44 423 569565

(A) NAME: Mr Keith Phillips
(B) TITLE: Manager
(C) TELEPHONE #/ FAX #:
(D) DEPARTMENT: Analytical Chemistry
(E) INSTITUTION: Hazleton UK
(F) MAILING ADDRESS: Otley Road, Harrogate
(G) STATE/ZIP: North Yorkshire HG3 1P

2.PROJECT TITLE: Determination of personal exposures to Environmental Tobacco Smoke in British non-smokers

3. KEY WORDS. PLEASE PROVIDE THREE (3) KEY WORDS WHICH WILL BE USED AS REFERENCE HEADINGS: Environmental Tobacco Smoke

4 INSTITUTION NAME AND ADDRESS OF INSTITUTION RESPONSIBLE AND ACCOUNTABLE FOR DISPOSITION OF FUNDS AWARDED ON THE BASIS OF THIS APPLICATION

(A) INSTITUTION: Hazleton UK
(B) STREET ADDRESS: Otley Road
(C) CITY: Harrogate
(D) STATE/ZIP: North Yorkshire HG3 1PY

5. LOCATION LIST LOCATION WHERE RESEARCH WILL BE CONDUCTED *IF OTHER THAN INSTITUTION IDENTIFIED IN #4 ABOVE*

(A)

(B)

6 INCLUSIVE DATES AND TOTAL COSTS OF THIS SPECIFIC PROJECT RELATED TO EACH 12 MONTH PERIOD IF MORE THAN ONE YEAR IS REQUIRED TO COMPLETE PROJECT. SUMMARIZE FROM BUDGET PAGE. ITEM 12(J). IT MUST BE UNDERSTOOD THAT AWARDS FOR 2ND AND 3RD PERIODS ARE DEPENDENT ON CENTER APPROVAL OF CONTINUATION APPLICATION.

	INCLUSIVE DATE		TOTAL COST
(A) 1ST 12 MONTH PERIOD	September 1992	THRU August 1993	125,000-00 POUNDS STERLING
(B) 2ND 12 MONTH PERIOD IF REQUIRED	-	THRU -	$
(C) 3RD 12 MONTH PERIOD IF REQUIRED		THRU	$

7 INSTITUTIONAL OFFICER NAME, TITLE AND TELEPHONE NUMBER OF INDIVIDUAL AUTHORIZED TO SIGN FOR THE INSTITUTION IDENTIFIED IN #4 ABOVE. IT IS UNDERSTOOD THAT THE OFFICER, IN APPLYING FOR A CONTRACT, HAS READ AND FOUND ACCEPTABLE THE CENTER'S MANAGEMENT OF RESEARCH CONTRACTS AND CONTRACT ADMINISTRATION POLICY (other than the payment schedule)*

(A) NAME: Mr M Wilson
(B) TITLE: Contracts Administrator
(C) TELEPHONE: 44 423 500011
(D) SIGNATURE OF INSTITUTIONAL OFFICER: M. Wilson
(E) DATE: 7 September 1992

10 &PRELIMINARY STUDIES* Page 8
(A) FEASIBILITY OF PROPOSED RESEARCH
(B) QUALIFICATIONS OF INVESTIGATOR

8. AIMS - Page 5

11 &EXPERIMENTAL PLAN* Page 9
(A) DESIGN
(B) METHODS
(C) ANALYSIS OF DATA
(D) INTERPRETATION OF RESULTS
(E) TIMETABLE FOR THE INVESTIGATION
(F) LITERATURE CITED

9. SIGNIFICANCE OF PROPOSED WORK - Page 6
(a) Background
(b) Literature
(c) Identification of gaps in proposed research area
(d) Project importance

12 & AVAILABLE FACILITIES AND RESOURCES Page 13

XXXXXXXXXXXXXX

* APPEND AS MUCH MATERIAL AS REQUIRED. TYPE, SINGLE SPACE. USE 8-1/2 X 11 WHITE PAPER AND LABEL EACH SHEET WITH NAME OF THE PRINCIPAL INVESTIGATOR IN THE UPPER RIGHT HAND CORNER AND PAGE NUMBER AT THE BOTTOM. CONSECUTIVELY NUMBER EACH ADDENDUM BEGINNING WITH PAGE 5. DO NOT INSERT PAGES BETWEEN PAGES 1 AND 6, E.G., 2A, 2B, 3A, ETC. INCLUDE NINE COPIES AND AN ORIGINAL. IF SENDING PHOTOGRAPHS, INCLUDE 2 ORIGINAL SETS. NOTE: EACH OF THE NINE COPIES MUST BE PLACED IN A BINDER PER MAILING INSTRUCTIONS.

* Please see preferred method of payment on Hazleton Quotation.

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HUK Study no 12/64

12.BUDGET. Detailed specific needs for the first 12-month period. Estimate category sub-totals for 2nd and 3rd periods, if required Append justifications.

(a) Salaries. List personnel by name and title. Indicate individuals % time to be spent on this project.	$ 1st period	$ 2nd period	$ 3rd period
% Professional:			
% Technical:			
% Other:			
Fringe benefits payable at institution s rate of %			
Category (a) Sub-Total			
(b) Consultants (per diem, travel & expenses):			
Category (b) Sub-Total			
(c) Supplies & Expense: Consumables (by category)			
Animals and related costs			
Other expenses (itemize)			
Category (c) Sub-Total			
(d) Travel Expenses:			
Category (d) Sub-Total			
(e) Alterations and Renovations			
Category (e) Sub-Total			
(f) Sub-contracts			
Category (f) Sub-Total			
(g) Equipment			
Category (g) Sub-Total			
(h) TOTAL DIRECT COSTS			
(i) Indirect costs not to exceed 25% of the sum of (a) thru (f)			
(j) TOTAL PROJECT COSTS			

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13. BUDGET

	Pounds Sterling
Pilot Study (10 volunteers)	7,500
Main Study (minimum of 280 volunteers)	
• Volunteer recruitment, administration, reimbursement	24,500
• Collection/delivery of kits; equipment maintenance	9,500
• Analytical phase, to include method development/ validation and routine analysis of samples for total particulates, nicotine, UVPM/FPM, solanesol and salivary cotinine	75,000
• Prepare a report and a manuscript for publication	8,000
TOTAL	**125,000**

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14 12. BIOGRAPHICAL SKETCH of all professional personnel listed in 12(a). Append. Please include the following Name, title, education, scientific field, major research interest, research and/or professional experience and publications. (Limit list of publications to the 20 most important and/or relevant.)

See Appendix C

15 13. a) Are HUMAN SUBJECTS to be used in this research? _____ Yes _____ No
If yes, attach Institutional Review Board approval for procedures involving human subjects.

See Appendix D

b) Are LABORATORY ANIMALS to be used in this research? _____ Yes _____ No
If yes, attach Institutional Animal Care and Use Committee approval for procedures involving animals.

Not applicable

16 14. SIGNATURE OF PRINCIPAL INVESTIGATOR. It is understood that the applicant in applying for a Contract has read and found acceptable the Statements of Policy and Terms Under Which Project Contracts Are Made appearing in the application package. **(other than payment schedule)**

K. Phillips 12 August 1992

Signature of Principal Investigator Date

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PHILLIPS

8 AIMS

The broad objective of the proposed work is to determine, through a variety of inter-related measures, the extent of exposure to ETS in typical British non-smokers.

The specific aims of the project are as follows:

1. To determine, in non-smoking British volunteers, the range and median levels of 24 hour exposure to nicotine and to ETS-related particulates.

2. To assess the contribution of exposure to ETS from different environments such as homes, the workplace and leisure and travel situations.

3. To assess whether non-smokers who are married to smokers have significantly higher exposures to ETS than non-smokers married to non-smokers.

4. To evaluate the extent of correlation between the different methods of exposure determination; questionnaires, salivary cotinine measures and personal monitoring of exposures to airborne constituents.

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PHILLIPS

9. SIGNIFICANCE OF PROPOSED WORK

a) Background

Two approaches have been used to assess whether there is any risk associated with exposure to ETS. One is based on epidemiology and the other based on the quantities of smoke constituents to which non-smokers are exposed. Further information is required on typical exposure levels in order to address questions relating to epidemiology studies and to obtain a better assessment of how much ETS people are exposed to.

Most of the information about the exposure of non-smokers to ETS is based on measurements of ETS levels in locations such as homes, offices and restaurants with assumptions about the time spent in these locations. There have been several such studies, particularly in the USA, but not enough to characterise properly the range of ETS exposure of non-smokers. It is, therefore, important to obtain further information for a variety of other situations, including different countries with various climates and lifestyles.

Surprisingly, there have, until recently, been few attempts to measure exposure of people directly as they go about their normal lives, moving from location to location, even though this approach should provide more realistic results than those calculated from ETS levels in various locations. Although this personal monitoring technique has been common practice in the industrial hygiene field for several years, it is only recently that the analytical methodology has been refined sufficiently to allow ETS measurements to be carried out by this approach. A few ETS exposure studies of this type have now been completed or are underway.

Nevertheless, further studies in a variety of countries are still required in order to obtain sufficient information with which to address some of the important ETS issues.

Although levels of both nicotine and ETS particles have been determined in several studies of locations, personal monitoring studies have tended to measure nicotine but not particles. In view of the limitations of nicotine as a marker for ETS and the importance often attached to particles, there clearly is a need for complementary personal monitoring studies in which ETS particles are also measured, especially now that the UVPM (ie. ETS particulate matter measured by ultra-violet light), FPM (ie. ETS particulate matter measured by fluorescence) and solanesol methods are available for estimating the ETS contribution to total particles.

A criticism of existing epidemiological studies of ETS is that they failed to include a direct measure of exposure level. Spousal smoking has frequently been used as an index of exposure in these studies but the validity of this approach is open to question. It is, therefore, important to determine whether reported extent of spousal smoking correlates with directly measured exposure. For the same reasons, it would be useful to determine how well directly measured ETS exposure can be predicted by questionnaire or by measurements of salivary cotinine since these approaches are also used as an alternative to direct measurements. It would also be useful to establish how peoples' personal assessment of their exposure compares with their measured exposure.

Smoking bans are being introduced in the workplace and in various public leisure and travel situations. It would be helpful to obtain further information on the extent of exposure in these situations to assess how each contributes to overall exposure.

The Study proposed here will help to address these issues.

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b) **Literature**

Perhaps the most extensive published evaluation of data related to ETS exposure is the monograph recently published by Guerin et al (Guerin, Jenkins and Tomkins, The Chemistry of Environmental Tobacco Smoke: Composition and Measurement, Lewis Publishers Inc. 1992). In this review of the existing literature, fourteen field studies of nicotine levels and twenty three field studies of particulate levels were tabled. Only one these studies referred to data acquired in the United Kingdom and so there is little to base comparisons in the literature between the predominately US based literature and a United Kingdom situation.

The same monograph briefly discusses the literature related to personal monitoring and biomarker assays. One personal monitoring study (Proctor et al, Environmental International 17, 287-297) measured personal exposures to nicotine and measured salivary cotinine levels in non-smoking British women. This study suggested a lack of correlation between cotinine and nicotine exposure levels. However, the study was small (50 subjects) and made no assessment of particulate exposures. US data on particulates (Spengler et al, Environmental Science and Technology, 19, 700-706, 1985) reported that 24 hour exposures to particulates were around 40 ug/m3 higher in those living in smokers' homes compared to non-smokers homes'. However, these researchers used comparative location techniques rather than chemical apportionation to determine the ETS contribution to particulates.

c) **Identification of gaps in proposed research area**

Our proposal addresses several gaps in the literature pertaining to the issue of population exposure to ETS. These are:

1. The sparsity of data specific to the United Kingdom. As far as we are aware there is only one UK based published study that has attempted to resolve the issues addressed in our proposal. Because of this it is uncertain whether the larger US database can be applied to the UK.

2. Little or no data exist on particulate exposure directly related to ETS as measured by chemical apportionation techniques.

3. The comparison of exposure assessment techniques (questionnaires versus chemical monitoring versus biomarker measurements) has rarely been addressed in studies measuring more that two of these comparative measures. The proposed study would compare six different measures (questionnaire, nicotine exposure, UV-PM exposure, Fluorescence-PM exposure, solanesol and salivary cotinine).

d) **Project importance**

Several agencies are currently considering the potential effects of exposure to ETS. In the United Kingdom, the Independent Scientific Committee on Smoking and Health stated it its Fourth report published in 1988 that it is recognised that the whole area of investigation of the composition and concentration of ETS is a difficult one and that it would keep the issue under review as new research findings became available. UK specific data would presumably be of value to this committee. On a broader basis, the investigation should prove useful in terms of an example of the use of personal monitoring techniques for investigating exposures to substances found in the environment.

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Source: https://www.industrydocuments.ucsf.edu/docs/njlm0000

10 PRELIMINARY STUDIES

a) Feasibility of the proposed research

A novel active monitoring device, which allows the simultaneous collection of airborne nicotine and particulates has been devised for this experiment. The effectiveness of this device has been evaluated in controlled experiments and we are confident that the collection technique will appropriately represent the personal exposures. The design and function of this device is described fully in the experimental plan. Apart from this, all of the methods proposed are standard and appear in the peer-reviewed literature.

b) Qualifications of investigator

The curriculum vitae of all the key investigators are appended to this proposal. The Institution, Hazleton UK, is experienced both in subject interview techniques and in the analysis if environmental and biological samples.

A profile of the company is attached to this proposal.

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11 EXPERIMENTAL PLAN

a) Design

The following is a brief description of the study design. 300 non smokers will be randomly selected from an existing database of 11,000 subjects held by GHBA/Hazleton Clinics in Leeds UK.

Either five or six volunteers will be studied each day such that eleven subjects will be studied every two days, including weekends. Each volunteer will be monitored for a continuous period of 24 hours.

The volunteers will all be from Yorkshire in the North of England, and will be selected to be representative in terms of age, sex and locality (urban/rural).

Their exposure to nicotine, TSP, UV-PM (particulates measured by UV light) F-PM (particulates measured by fluorescence) and solanesol will all be monitored.

At the beginning and the end of the monitoring period, saliva samples will be taken. The volunteers will maintain a diary throughout the monitoring period. A questionnaire will be completed at the end of the 24 hour period.

Prior to the start of the main study (approximately 3 to 4 weeks) a "pilot study" or trial will be conducted using ten volunteers. The purpose of the trial is to assess all aspects of the main study including collection, analysis and questionnaire completion and to highlight any problems that might occur in the main study.

b) Methods

i) Subjects

300 non-smokers will be randomly selected from an existing database of 11,000 subjects held by GHBA/Hazleton Clinics in Leeds, UK. All volunteers are to be non-smokers aged between 20 and 60 years of age. Subjects will reside in the Leeds and Harrogate area in the North of England and they will be distributed based on age, sex and locality (urban/rural).

A pre-acceptance questionnaire will be used to select an excess of volunteers so that in the event of drop-outs suitable replacement candidates can be selected. The volunteers will be provided a financial incentive for their involvement in the study.

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ii) **Sample delivery and collection**

A minimum of 280 volunteers results are required. To acheive this, five or six subjects will be monitored daily producing 11 samples every two days over a period of fourteen consecutive days. Thus 70 results will be obtained in a two week period. This regime will be repeated on three consecutive occasions.

The personal monitors will be delivered to the volunteers at pre-determined locations and times and will be collected as close as possible to 24 hours later. The monitor pump will be turned on and off by the investigators and not by the subjects. Times of start and finish, as well as recorded cycles of the pumps, will be recorded.

Saliva samples will be taken from each subject at the beginning and at the end of the 24 hour sampling period.

Questionnaires will be completed by the investigator who will ask a series of pre-determined questions, coded for later analysis. These questions will be asked at the end of the sampling period. The volunteers will also carry a time-activity diary in order to record observations throughout the monitoring period.

iii) **Collection and analysis of airborne nicotine and particulates**

The collection of these analytes relies upon the use of a compact collection system which is worn by the subject in order to sample the air to which he/she is exposed. It consists of two filters in series connected to a sampling pump. The first filter collects the total particulates and the second, which is acid-treated, traps nicotine vapour.

Air is drawn through the filters by a small, quiet, battery powered pump which is concealed in a small bag worn at the subject's waist level. The pump is set at a flow rate of 139 ml/min so that a total volume of 200 litres is drawn through the pump during the 24 hour monitoring period.

The filter holder is attached to a rigid wire "necklace" which holds the monitor in place and allows ease of removal. A clip will be provided as an alternative to the necklace.

During periods of sleep or bathing the monitor will be taken off but be placed close to the subject. Such events will be noted in the time-activity diary.

In brief, the analytical methods to be used are as follows:

The analysis of the nicotine and 3-Ethenylpyridine contained on the acid treated filter involves extraction into dis-isopropyl ether (DIPE) (containing 0.1m/l triethylamine and 2.0 mg/l N-ethylnornicotine (internal standard) from sodium hydroxide which is used to basify the filter.

The DIPE extract is then analysed by capillary gas chromatography with nitrogen specific detection.

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The total suspended particulate concentration is determined gravimetrically by the difference in weights of the front teflon pad before and after sampling.

After weighing, the pad is extracted in methanol in order to determine UV-PM, F-PM, solanesol and any residual nicotine and 3-Ethenylpyridine that might have been trapped on the front filter.

iv) **Collection and analysis of saliva**

Saliva will be collected from each subject immediately before and after each monitoring period. This will be achieved by the subject chewing on a dental swab for around a minute. The swab is then returned to the laboratory sealed in its salivette container.

The saliva is recovered by high speed centrifuge for two minutes. Cotinine and N-ethylnorcotinine (internal standard) are extracted from the saliva and the extract analysed by GC with mass selective detection.

v) **Detection limits**

Under the sampling regime described, the detection limits for the various analytes are expected to be as follows:

Total particulates	20 $\mu g/m^3$ as ETS particulates
UV-PM	5 $\mu g/m^3$ as ETS particulates
F-PM	5 $\mu g/m^3$ as ETS particulates
Solanesol	10 $\mu g/m^3$ as ETS particulates.
Nicotine	0.5 $\mu g/m^3$
3-Ethenylpyridine	0.5 $\mu g/m^3$
Salivary cotinine	0.5 $\mu g/ml$

vi) **Quality Control**

The study will be performed where appropriate in accordance with the Good Laboratory Practice provided as guidelines of the UK Department of Health compliance programme (1989). Where appropriate all work will be performed under Hazleton's standard operating procedures.

Any deviations from the protocol will be recorded as a file note against the raw data and highlighted in the final report.

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PHILLIPS

c) **Analysis of data**

Subject information and corresponding analytical data will be compiled in a database as the study progresses.

Computation of means and ranges for each of the analytes and correlations between the different analytes will be achieved through standard statistical procedures.

d) **Interpretation of the results**

The results will be reported both as a detailed research findings report to the Center for Indoor Air Research and if the data allow, as a publication for a peer-review scientific Journal.

e) **Timetable of investigation**

Should approval be received, the pilot phase of the study could begin within one month. Field sampling would occur over a period of around two and one half months. Data analysis and reporting is expected to be complete three months after the completion of sampling.

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12 AVAILABLE FACILITIES AND RESOURCES

Hazleton UK is the European Headquarters of Hazleton Corporation, a wholly owned subsidiary of Corning Laboratory Services Inc. The company provides a wide range of product development and safety evaluation services to the pharmaceutical, agrochemical and chemical industries.

The laboratories at Harrogate, which occupy 185,000 square feet on a 20 acre site, are engaged in general and reproduction toxicology, molecular toxicology, metabolism and pharmacokinetics and biological and chemical analysis. The 50 bed GHBA/Hazleton Clinic, Leeds, undertakes clinical pharmacology studies in healthy volunteers and a variety of patient population groups.

All studies conducted by Hazleton and GHBA satisfy requirements for Good Laboratory and Good Clinical Practices (GLP and GCP) respectively.

Of the 625 staff, 159 are degree level and 39 doctorate level. Five percent of time is devoted to training, as part of the company's Total Quality Management programme.

The modern analytical laboratories are particularly well equipped to undertake the proposed study and the Principal Investigator has direct experience of tobacco smoke analysis studies.

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APPENDIX 1.1

CVs FOR KEY INVESTIGATORS

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R: REDACTED MATERIAL

PE11

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: PHILLIPS, Keith

Date of Birth: REDACTED

Job Title: Manager, Analytical Chemistry

Education:

1960-1965	'O' Levels in English Language, English Literature, Welsh, French, Geology, Physics, Maths, Chemistry, Special Arithmetic
1965-1967	ONC Denbighshire Technical College Chemistry, Mathematics, General Studies.
1967-1969	HNC Denbighshire Technical College Chemistry, Special in organic Synthesis.
1969-1970	GRIC University of Salford, Manchester (Part 1)
1973	Elected Licentiate of the Royal Society of Chemistry
1982	GRSC (by counselled experience).
1991	Elected Fellow of the Royal Society of Chemistry.

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2. PRESENT EMPLOYMENT

Hazleton UK

1989-Date	Head of Analytical Chemistry Responsible for Residues Chemistry, PhysicoChemistry, Chemistry Services. The service offered encompasses GC, HPLC, FTIR, GCMS, LCMS for the Agrochemical Industry.
1985-1989	Head of Chemistry Services Responsible for the Instrument Laboratory, Mass Spectrometry facility, and Formulation Analysis comprising of Tobacco, Toxicology Support and Pharmaceutical Analysis. Responsible for scheduling and revenues projection for all sections within Chemistry Operations and provision of PBUs for business development. Also interfacing between operations and BD for present and forecasted workloads.
1983-1985	Head of Chemistry Operations Responsible for all aspects of the administration, organisation and management of Chemistry Operations ie Analytical and Metabolic. This covers the actual performance, both scientific and financial, of all the projects carried out for clients within chemistry and meeting the standards laid down by company policy. The scope includes all the resources, human and physical attached to this area, and demands motivation of all the people involved. Also responsible for ensuring the smooth and efficient day-to-day running of the profit centre by active participation and control and by maintaining a close liaison with the

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Director of Chemistry and the Principal Scientist for Metabolism and Pharmacokinetics in regard to proposal activities and project status.

1978-1983 Head of Central Dispensary
Initially made responsible for setting up the facility and resources to run it. Responsible for the management of all test articles received at Hazleton, in accordance with Good Laboratory Practice (GLP) regulations. The formulation of all the materials using detailed Standard Operating Procedures, training staff, preparation and implementation of career development programmes, competence check lists etc. Also responsible for all financial aspects of the department.

1974-1978 Senior Residues Analyst
Responsible for the development/evaluation and subsequent application of many analytical procedures for measurement of crop protection chemical residues. Project Manager for a series of plant and soil metabolism studies using mainly radiochemical techniques.

3. PAST EMPLOYMENT

1972-1974 Tobacco Research Council Laboratories
Analyst/Synthetic Chemist
Primarily concerned with investigations into the possible effects of tobacco smoking on health.
Responsible for the synthesis of an unsaturated precursor subsequently reduced using tritium gas to give a high specific

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radioactivity material for inclusion in the tobacco. Also involved with the evaluation of 2, 4-D and 2, 4, 5-T as endogenous cigarette smoke markers.

1970-1972

Wellcome Foundation, Berkhamsted
Principal Senior Technician
Responsible for the day to day management of all senior and junior technicians and reported directly to the Head of the Chemotherapy Unit. Actively involved in the synthesis of cyclopropane carboxylic acid derivatives (chrysanthemates) subsequently used for synthesis of pyrethroids. Gained wide experience of Grignard reagents during this period of employment.

1965-1969

Monsanto Chemicals Limited, Ruabon
Trainee technician - Senior Technician
During the first 12 months became acquainted with the handling and use of organic chemicals and received training in basic laboratory techniques.
Final position was as a senior technician reporting directly to a senior chemist. Gained experience in the synthesis of a wide range of anti-ozonant compounds and their subsequent testing using a rheometer for the studies of rubber vulcanisation reactions.

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4. TRAINING COURSES

1971-1972	Interpretation of NMR, UV, IR spectra held at Berkhamsted.
1974	Attended a residential course on radioisotope techniques at the University of Loughborough.
1980	Attended a residential Management Training Course.
1981	Report writing course for chemists.
1982	Management Training Course (1 week residential).
1983/4	Management/Supervisor training course.
1985	Management Course/Time Management.
1986	Report Editors course for Chemists/Scientists.
1987	Total Quality Course.
1988	GLP in the Chemical laboratory RSC - ICI Wilton
1989	Quality Refresher Course.
1989	LIMS for the Chemistry Laboratory RSC London.
1989	Residue levels on crops and their analysis (BCPC London)
1989	PC training (Word Perfect).

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1990	COSHH in laboratories.
1990	Management Skills course.
1991	Management Skills course.

5. PROFESSIONAL SOCIETIES

REDACTED

6. SCIENTIFIC PUBLICATION

Synthesis of High Specific Activity Tritium Labelled Dotriacontane.
Journal of Labelled Compounds and Radiopharmaceuticals
Vol XIV, No 2 1978.

7. OTHER RELEVANT DETAILS

1978	Worked in a problem solving role at the Agrochemical Division of Bayer AG in Leverkusen West Germany in their Pesticide Residues Laboratory. This work in West Germany enabled Hazleton Laboratories to complete a project on behalf of the sponsor and submit a report to the PSPS.
1985	Co-author of Chemistry Division's Career/training programmed in chemistry.
1988	Development of HPLC/GC training course with Leeds Polytechnic. Subsequently modified and 25 chemists trained extensively in chromatography over 1-2 years.
1990	Developed brochure and overhead presentation on COSHH in laboratories for HUK. Presentation made to Health and Safety Executive.

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1990	Member of the HUK COSHH Committee.
1991	Involved with RSC Chemistry at Work Exhibitions involving schools in Yorkshire.

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R: REDACTED MATERIAL

PE11

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: HOUSEMAN. Terence Henry

Date of Birth: **REDACTED**

Job Title: European Industry Development Manager

Education:

1961-1965 University of Bradford
1st class Honours Bachelor of Technology Degree in Industrial Chemistry (specialising in high polymer chemistry and chemistry of dye stuffs).

1967-1970 University of London
PhD thesis entitled "Radiochemical studies of the oxidation of natural rubber"

2. PRESENT EMPLOYMENT

Hazleton UK

1991- European Industry Development Manager

1987-1991 Head of Business Development, Chemical and Medical Sciences.
Responsible for a complete commercial/business support function which embraces and oversees all financial

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Source: https://www.industrydocuments.ucsf.edu/docs/njlm0000

budgeting, planning and business development activities of the division.

1985-1986 Director of Chemical and Medical Sciences
Responsible to the Managing Director for all scientific and commercial aspects of the Division, which now incorporates Hazleton's clinical activities.

1980-1985 Director of Chemistry, Responsible to the Managing Director for all aspects of the administration, organisation and management of assigned operating areas, including Analytical Chemistry, Metabolism and Pharmacokinetics and HAZLETON Masspec (and until recently, Central Dispensary). Also responsible for the commercial activity of the Division.

1976-1979 Head of Chemistry and Metabolism
Responsible to the Director of Research Operations for all operational and scientific aspects of Analytical Chemistry, metabolism and Pharmacokinetics and Central Dispensary, including establishment of the latter. This also included delegated responsibility for commercial activities such as business development.

1974-1976 Head of Radio and Analytical Chemistry
Responsible for establishing and developing the department as a viable profit centre, with responsibility for all operational and scientific aspects and delegated responsibility for business development.

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3. PAST EMPLOYMENT

1971-1974	Tobacco Research Council Laboratories Head of Chemistry Research Services (and Radiological Protection Officer) Responsible for providing a chemistry service (analytical and synthetic) to other departments within the company, eg Pharmacology, Biology, and collaborating with external TRC grantees.
1970-1971	Tobacco Research Council Laboratories Radioanalytical Chemist Responsible for studying the smoke transference of exogenous and endogenous tobacco constituents to mainstream and substream smoke with the ultimate objective of determining the fate of constituents in the human smoking situation.
1965-1970	Natural Rubber Producers' Research Association Radioanalytical Chemist Responsible for studying mechanisms of oxidative mainstream and cross-link scissions in vulcanized and unvulcanized natural rubber. Radioanalytical techniques featured strongly in this work.
1962	Undergraduate Associated Chemical Companies Ltd, Central Research Laboratories Industrial training period
1963	Sandoz Products (Dye Stuffs) Ltd Industrial training period

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1964	Undergraduate Natural Rubber Producers' Research Association Industrial training period

TRAINING COURSES

1972	Radiological Protection Course - Harwell
1980-1984	HLE Senior Management residential training course Plus numerous specialist short courses on accountancy, management, etc.
1985	Organisation Development - Scott Grant Sales Development - Industrial Training Services Ltd Building an effective team - Industrial Training Services Ltd
1988	Developing Key Marketing Skills - Cranfield School of Management
1989	Good Clinical Practices Workshop - Oxford Workshops
1989	Customer Service Worksnop
1991	Customer Action Planning Systems - Corning Inc Management Skills Course - Hazleton Training Unit Senior Management Team Building Workshop - Hazleton Training Unit Presentation Skills - Hazleton Training Unit
1992	Negotiation Skills - Hazleton Training Unit

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5. PROFESSIONAL SOCIETIES

REDACTED REDACTED

6. SCIENTIFIC PUBLICATIONS

Barnard, D, Houseman, T H, Porter, M R and Tidd, B K (1969) "Thermal racemization and cis, trans - isomerization of allylically unsaturated di - and poly-sulphides: a mechanism involving branched sulphur chains".
Chem. Comm. - 371

Barnard, D and Houseman, T H (November 1969) "The application of radiochemical methods to the study of oxidation of natural rubber". Symposium of Oxidation, Hall of Fame Ceremony, Institute of Polymer Science. Adron University.

Ayrey, G, Barnard, D and Houseman, T H (1971) "The use of radioisotopically labelled analytical reagents in organic chemistry".
Chem Rev 71 371

Barnard, D, Cain, M E, Cuneen, J I and Houseman, T H (1972) "Oxidation of vulcanized natural rubber".
Rubber Chem Technol, 45, 381

NB This paper was also presented at a meeting of the Division of Rubber Chemistry, American Chemical Society, Cleveland, Ohio, October 1971.
Ayrey, G, Barnard, D and Houseman, T H (1974) "The synthesis of tritium labelled dialkenyl sulphides structurally related to sulphur crosslinks in vulcanized natural rubber".
J Labelled Compound, 10, (1), 121

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Source: https://www.industrydocuments.ucsf.edu/docs/njlm0000

Houseman, T H and Heneage, E (1973)
"Studies of cigarette smoke transfer using radioisotopically labelled tobacco constituents. Part I - The preparation of radioisotopically labelled cigarettes".
Beitrage Zur Tobakforschung, 7, (3), 138

Houseman, T H (1973)
'Studies of cigarette smoke transfer using radioisotopically labelled tobacco constituents. Part II - The transference of radioisotopically labelled nicotine to cigarette smoke".
ibid, 7, (3), 142

NB This paper was also presented at the 25th Tobacco Chemists Res Conf. Louisville, Kentucky, USA. 1971

Davis, B R. Houseman, T H and Roderick, H R (1973) "Studies of cigarette smoke transfer using radioisotopically labelled tobacco constituents. Part III - The use of dotriacontane-16, 17-^{14}C as a marker for the deposition of cigarette smoke in the respiratory system of experimental animals".

Armitage, A K, Houseman, T H, Turner, D M and Wilson, D A (1974) "The evaluation of a machine for introducing tobacco smoke into the lungs of anaesthetized animals during spontaneous respiration".
Quart J Exp Physiol, 59, 43

Armitage, A K, Houseman, T H and Turner, D M (1974)
"The transfer of endogenous and exogenous radioisotopically labelled nicotine to mainstream cigarette smoke and its absorption into the blood of anaesthetized cats".
ibid, 59, 55

Hopper, J B and Houseman, T H (1974)
"The transference of endogenous and radioisotopically labelled exogenous nicotine to cigar smoke".
Tobacco Science, 18, 160

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Source: https://www.industrydocuments.ucsf.edu/docs/njlm0000

NB This paper was also presented at the 27th Tobacco Chemists Res Conf, Winston-Salem, North Carolina, October 1973.
Armitage, A K, Dollery, C T, George, C F, Houseman, T H, Lewis P J and Turner, D M
"Absorption and metabolism of nicotine by man during cigarette smoking".
Brit J Clin Pharmac

Armitage, A K, Dollery, C T, George, C F, Houseman, T H, Lewis, P J and Turner, D M (1975) "Absorption and metabolism of nicotine from cigarettes".
Br med J, 4, 313

Armitage, A K, Dollery, C T, Houseman, T H, Kohner, E M, Lewis, P J and Turner, D M (1977)
"Absorption of nicotine by man during cigar smoking".

Houseman, T H, Macfarlane, E A, Pullinger, D H, and Simons P J (1977).
"A single animal smoking system for exposing rats and other rodents to cigarette smoke".
J Aerosol Sci, 8, 111

Houseman, T H and Pullinger, D H
"Dosimetry of cigarette smoke (and other aerosols) in laboratory animals".
Clinical Toxicology, Proceedings of the European Society of Toxicology, Volume 18, ICS No 417, Amsterdam - Oxford, Exorpa Medica, 1977, pp 265 - 266

Binns, S H, Houseman T H and Phillips, K (1978)
"Synthesis of high specific activity tritium - labelled dotriacontane P
J Labelled Compounds and Radiopharmaceuticals, 14, (2), 163
Armitage, A K, Dollery, C T, Houseman, T H, Kohner, E M, Lewis, P J and Turner, D M (1978)
"The absorption and metabolism of nicotine from cigars".
Clin Pharmcol Ther, 23, (2), 143

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Source: https://www.industrydocuments.ucsf.edu/docs/njlm0000

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2. SCIENTIFIC PRESENTATIONS.

Barnard, D, and Houseman, T H (November 1969). "The application of radiochemical methods to the study of oxidation of natural rubber". Symposium on Oxidation, Hall of Fame Ceremony, Institute of Polymer Science. Akron University, November 1969.

Houseman, T H, and Heneage, E (1973).
"Studies of cigarette smoke transfer using radioisotopically labelled tobacco constituents. Part I - The preparation of radioisotopically labelled cigarettes".

Hopper, J B and Houseman, T H (1974)
"The transference of endogenous and radioisotopically labelled exogenous nicotine to cigar smoke".

3. OTHER DETAILS

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Source: https://www.industrydocuments.ucsf.edu/docs/njlm0000

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PE11

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: TENNANT, Karen Ann (née Bremner)

Date of Birth: REDACTED

Job Title: Scientist and Study Director, Department of Biopharmaceutical Analysis

Education:

1982 - 1986 BSc. (Hons in Applied Chemistry) Coventry Lanchester Polytechnic

2. PRESENT EMPLOYMENT

Hazleton UK

1990 July - Scientist and Study Director, Department of Biopharmaceutical Analysis (formerly Bioanalytical). Responsibilities as for Study Director role below. Since September 1991 responsible for Special Methods group; responsible to the Head of Department

1989 - 1990 June Study Director, Bioanalytical Department. Responsible for the supervision of projects within the department to ensure good scientific and commercial management. This includes close liaison with sponsors as well as the Section Manager.

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2. PRESENT EMPLOYMENT - continued

1989 - 1990 June	Supervision and training of junior and graduate staff is a further responsibility
1986 - 1989	Study Supervisor, Biofluids Analysis. Responsible for the day to day performance of routine assays and assisting in method development and validation work for the measurement of drug levels in body fluids using gas and high performance liquid chromatography. Supervision of technical staff allocated to specific studies

3. PAST EMPLOYMENT

1984 - 1985	Ministry of Agriculture, Fisheries and Food. Industrial Placement for BSc course. Analysis of animal feeds, soils and dairy produce, including investigation into sulphate determination using HPLC and Dionex Ion Exchange Chromatography

4. TRAINING COURSES

1987	Jones Chromatography Solid Phase Extraction (one day seminar)
1988	Jones Chromatography Advanced Solid Phase Extraction (one day seminar)
1988	Total Quality Phase I Course (HUK)
1988 - 1989	Chemistry Training Modules for Study Supervisors

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4. TRAINING COURSES - continued

1989	Hazleton UK Course in Chromatographic Techniques at Leeds Polytechnic (10 day course)
1989	ESA Coulochem Electrochemical Detection (2 days, Severn Analytical)
1989	Total Quality Refresher Course (HUK)
1990	2nd International Symposium on Pharmaceutical and Biomedical Analysis (took part in poster presentation) (3 days)
1990	The Royal Society of Chemistry (Analytical Division, Autumn meeting) "Biomedical and Pharmaceutical Chemistry". (2 day seminar)
1990	"Advances in Capillary Gas Chromatography" by Professor Walter Jennings (1 day)
1990	World Class Quality Course (HUK)
1991	Management Skills Course (HUK 5-day)
1991	Bioanalysis of drugs, including anti-allergics and anti-asthmatics. 9th International Bioanalytical Forum (4-day seminar)
1991	Capillary Chromatography Seminar (1-day) (Restek Corporation/Thames Chormatography)

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5. PROFESSIONAL SOCIETY

Member of the Royal Society of Chemistry

Signature: Karen Tennant Date: 4 February 1992

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PE11

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: MOORE, Jeff

Date of Birth: REDACTED

Job Title: Study Director, Bioanalytical Department

Education: 1979-1982 Kingston Polytechnic
B.Sc. Bioanalytical Science Option of
Applied Science degree 2(i)

2. PRESENT EMPLOYMENT

Hazleton UK

1986- Study Director in Bioanalytical Department. Responsible for the supervision of projects within the section to ensure good scientific and commercial management. This includes close liaison with clients as well as the section manager. Supervision and training of junior and graduate staff is a further responsibility.

3. PAST EMPLOYMENT

1983-1986 Beecham Pharmaceuticals Research Division
Analytical Chemist in Pharmacokinetics Unit.
Responsible for method development and routine assay of biofluid samples generated by toxicology studies

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and clinical trials as well as the reporting and pharmacokinetic interpretation of results. Responsible for training of junior staff in the use of VG Multichrom data capture system.

4. TRAINING COURSES

1983	Pharmacokinetics Training Course (Dr. P.E. Coates DMPD Beecham Harlow)
1984	Laboratory Animal Handling (introductory course for potential Home Office licensees)
1984	Solid-Phase Extraction Techniques (Analytical Symposium)
1984	VG Multichrom Training Course
1985	Communication and Report Writing Workshop
1986	Statistics for Industry : 2 modules i) Basic statistical techniques ii) Statistics for Research and Development
1986	Pharmacokinetics and Drug Disposition
1987	Management and Supervision training course 8 one day modules (Scott-Grant)
1987	Report Writers Course
1987	Solid-Phase Extraction Techniques
1987	Total Quality Phase I Course
1988	Report Writers Refresher Course

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1988	International Symposium on Biomedical Applications of liquid chromatography (Bradford, UK).
1989	Total Quality Refresher Course
1989	Chemistry Training Modules for Study Supervisors
1990	2nd International Symposium on Pharmaceutical and Biomedical Analysis (York, UK).
1990	18th International Symposium on Chromatography (Amsterdam, Netherlands).
1990	World Class Quality Course

5. PROFESSIONAL QUALIFICATIONS

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6. PUBLICATIONS

1990	Automation of a HPLC assay for the determination of nicotine, cotinine and 3-hydroxycotinine in human urine. J. Biomed and Pharm Anal (Accepted for publication).
1990	On-line sample preparation and analysis of nicotine, cotinine and 3-hydroxycotinine and conjugates in human urine using a Gilson-AASP system. J. Chromatogr Biomed Appl (Accepted for Publication).

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HUK Study no. 12/64

PE11

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: FREEMAN, John Michael Howard

Date of Birth: REDACTED

Job Title: Senior Scientist, Residues Chemistry, Department of Metabolism and Environmental Chemistry

Education:

1958-1964	Reade Grammar School, Drax O level: English Language, English Literature, Art, French, History, Physics, Geography, Mathematics, Agricultural Science, Physics with Chemistry, Physics
1965-1967	Kitson College, Leeds ONC in Sciences
1967-1970	Leeds Polytechnic HNC in Chemistry
1970-1974	Sheffield Polytechnic BSc Hons in Applied Chemistry (2:2)

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2. PRESENT EMPLOYMENT

Hazleton UK

Mar 1991

Senior Scientist, Residues Chemistry
Study Coordinator responsible for coordinating the design and maintaining the Residues study schedules, and reporting performance statistics for Residues, Physical Chemistry and Environmental Fate. Also controlling the QA audit trail for these groups. The role also includes the collation of financial information and its provision to the Section Manager

1988 - Mar 1991

Senior Study Director, Residues Chemistry
Acted as the focal point of study control and has overall responsibility of the scientific and technical conduct of the studies, as well as the interpretation, documentation and reporting of results. Maintains close liaison with clients on scientific matters and study status. Prepares PBUs and protocols. Responsible for the supervision and training of four staff

3. PAST EMPLOYMENT

1984-1988

Senior Research Chemist at Dow Chemical Co, Letcombe Regis, Oxfordshire
Worked in the Residue Environmental Metabolism Group. Responsibilities included the supervision of students during industrial training, developing methods of analysis, liaising with various groups within the company, producing reports necessary for registration authorities, organisation and supervision of "one off"

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3. PAST EMPLOYMENT continued

	type residue studies, eg operator monitoring studies. Responsibilities also included the implementation of the Zymark laboratory robot to perform routine residue analysis. Acted as work permit signatory and first aider within the group
1980	Research Chemist at Dow Chemical Co Graduate Chemist at Dow Chemical Co
Aug 74 - May 77	Analytical Chemist at Ciba-Geigy Ltd, Whittlesford, Cambridge. Initially the same as above. Latterly was responsible for the determination of residues in a variety of matrices, working with one assistant
Jan 73 - Sep 73	Temporary Assistant at Ciba-Geigy Agrochemicals Ltd, Whittlesford, Cambridge. Assisted in the analysis of residues of pesticides and their metabolites in crops, soils and water, and also of the company's development and marketed products
Aug 71 - Dec 71	Temporary Assistant at the Ministry of Agriculture, Fisheries and Food, Harpenden. Assisted in inter-laboratory collaborative trials, the results of the work being forward to the PAC (Pesticide Advisory Committee).
1964-1970	Laboratory Assistant at BOCM Ltd, Selby. Assisted in the analysis of oils and fats, boiler waters and the raw materials of the cattle, pig and poultry feeds marketed by

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3. PAST EMPLOYMENT continued

the company. During the latter part of the employment, was involved in special projects, reporting directly to the Chief Chemist. Completed part-time studies, ONC Sciences and HNC in Chemistry, whilst in this job

4. TRAINING COURSES

Jun 1988	Quality course run by HUK
Mar 1989	Lotus Freelance 3.01, Manchester
Mar 1989	Follow-up Quality course run by HUK
Jul 1989	GLP course, Cambridge
1990	WordPerfect 5.1 run by HUK
Sep 1990	COSHH training course run by Occupational Hygiene Services at HUK
Dec 1990	5-day training course on "Management skills" run by HUK
Jun 1991	Lotus 123 course run by International Software at HUK

5. PROFESSIONAL SOCIETIES

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Signature: John [illegible] Date: 28 January 1993

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PE11 HAZLETON UK

CURRICULUM VITAE

1. PERSONAL DETAILS

Name: HOWARD, David Albert

Date of Birth: REDACTED

Job Title: Senior Scientist, Residues Chemistry, Department of Metabolism and Environmental Chemistry

Education:

1973-1977 University of Manchester Institute of Science and Technology
BSc Hons in Chemistry

2. PRESENT EMPLOYMENT

Hazleton UK

1986 - Supervisor, Instrument Laboratory and Chromatographic data processing; Data System Manager, Chemistry Services
Responsible for all personnel and equipment allocated to the Instrument Laboratory and Chromatographic data processing function in order to provide an efficient service to Chemistry operations. Includes identification of future requirements in terms of both human and physical resources and initiating action to ensure these are

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1987	HP3350A (LAS) System Managers Training Course (Hewlett-Packard)
1987	Management and Supervision Training Modules
1988	Fortran Computer Programming Course
1989	Lotus Freelance Plus Training Course
1989	Management of Information Systems and Information Technology
1989	Total Quality Refresher Course
1990	Wordperfect (Basic) Training Course
1990	Management Skills Course
1991	Use of Base-Deactivated HPLC columns
1991	Wordperfect (Advanced) Training Course
1992	Network Awareness
1992	Management Skills Course
1992	Paradox Introduction Training Course

5. PROFESSIONAL SOCIETIES

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Signature: C Howard Date: 5 May 1993

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